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SIDBERRY,H EXAMINER

18N1/1129

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ART UNIT	PAPER NUMBER
1813	34

DATE MAILED: 11/29/94

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 9/12/94 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 2-5, 7-10, 19-58, 62 are pending in the application.
   Of the above, claims 2-5, 7-10, 20-46, 47-58 are withdrawn from consideration.
2. ☒ Claims 1, 6, 11-18, 59, 60 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 19 & 62 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 9-89)

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The Examiner acknowledges the amendment filed 9/12/94 in response to the communication of 8/5/94.

The numbering of claims is not in accordance with 37 C.F.R. 1.126. The original numbering of the claims must be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When claims are added, except when presented in accordance with 37 C.F.R. 1.121(b), they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). Misnumbered claim 53 has been renumbered 62.

Applicant has also requested withdrawal of claims 47-52 from consideration. Claims 53-58 submitted 4/4/94 depend from claims 47-52 and will also be accordingly withdrawn from consideration.

Claims 59, 60 are cancelled. Claims 2-5, 7-10, 20-46 were withdrawn from consideration. Claim 61 is also withdrawn from consideration as being directed to a non-elected invention

Claims 1, 6, 11-18, 59, 60 are cancelled.

The remaining claims under examination are claims 19 and 62 which are directed to the UTAA antigen of 90-100 kd molecular weight and a method.

Applicant's arguments filed 9/12/94 and 4/4/94, have been fully and carefully considered, but they are not deemed to be persuasive.

Applicants' remarks directed to rejection(s) of claims which have been withdrawn are considered moot and will not be further

addressed.

The Examiner's remarks are directed to Applicants response as it may apply to the remaining claims under examination.

(1) Claims 19 and now 62 have been rejected under 35 U.S.C. § 101 because the claimed invention as claimed is inoperative and therefore lacks patentable utility and also under 35 USC 112, 1st paragraph as non-enabling.

Applicant has cancelled the claim(s) which recite "vaccine" and presented claim 62 which recites "antigenic composition". Applicant contends that the amendment to the claim now do not require or imply "successful cancer treatment". Accordingly a "sufficient utility lies in the fact that UTAA-compositions are useful in the preparation of antibodies useful in cancer diagnosis."

However, claim 19 is directed to a method for inducing or enhancing in a subject the production of antibodies reactive with tumor cells in the subject comprising administering the composition of claim 47 (62).

Although the claim includes limitations of inducing antibody, the Examiner can only conclude that the ultimate purpose of the induction of antibody by this method, is to cause some type of response in the subject with respect to the tumor cells present. Otherwise, it is unclear what the practical utility is of inducing antibody reactive with tumor cells in the subject. Applicant may contend that this is "merely" a method to generate antibodies to the antigen for diagnostic use. However, the typical methodology for raising monoclonal antibody is not by giving the subject the

antigen to induce antibodies reactive with tumor cells in the subject, but a subject is immunized with the antigen. Subsequently fusions are preformed, hybridomas are selected which are secreting the antibody reactive with the "antigen".

Furthermore the limitation "reactive with tumor cells in the subject" in the claim continues to suggest that Applicant intends to use the antigen composition a method of "cancer treatment".

The amendment to the claims also does not negate the statement at page 16 of the specification, where Applicant indicates that "the vaccine", now "antigenic composition" provides a method for inducing or enhancing in a subject afflicted with a cancer the production of antibodies reactive with the polypeptide, comprising administering to the subject an effective dose of the vaccine (antigenic composition) Further, Applicant indicates that the "antibody" produced in the individual after administration of the vaccine (antigenic composition) inhibits or treats the cancer. Thus, the ultimate "utility" of the composition and the resultant antibodies are to effect in vivo treatment of cancer.

In Paper Number 23, the Examiner indicated that "Applicants are claiming a vaccine (antigen composition) containing a specific protein UTAA which protein appears to possess diagnostic value, however no data has been provided showing that the protein is in any way useful as a composition effective against cancer." The specification does not set forth any data or experimental results documenting that the antigen can effect a treatment of cancer.

In fact, the presence of antibodies to UTAA in cancer patients underscores the unbelievability of the asserted utility, since

bodies appear no to be able to protect the patients" (see of the Office Action) or produce an effect on the cancer.

(2) With respect to the rejection under 35 USC 112, 1st paragraph, it is clear that as the specification fails to teach the administration of any composition which inhibits cancer in a subject, the specification has not taught how to use the composition.

If, it is Applicants intent to draft a claim directed to method of making antibody, then it is suggested that the claims be drafted to reflect such. For example, "a method of making antibody which is reactive with UTAA antigen comprising a step of immunizing subject."

Therefore the rejection of claims 19 and 62 under 35 USC 101 and 35 USC 112, 1st paragraph is maintained.

(3) The rejection of claims 18, 19, 47 under 35 USC 112, 2nd paragraph as being indefinite is obviated by the amendment to the claims.

(4) Claims 19 and 62 ~~is~~ are rejected under 35 U.S.C. § 102(b) as being anticipated by Gupta et al.

Gupta et al disclose the vaccination of melanoma patients with tumor cells, at least one of which (M14 cells) expresses melanoma tumor associated antigen. The cell line inherently produces UTAA antigen and the composition "comprises" the UTAA antigen. The claim language fails to exclude the entire cell as the claim recites "wherein the tumor antigen is identified as comprising UTAA subunit".

Claim 62 is rejected under 35 U.S.C. § 102(b) as being

anticipated by Real et al US Patent 4 562 160.

Applicant contends that the molecular weight of the UTAA antigen is "in the range of 590-620 kd under non-reducing conditions, in contrast the antigen of Real et al is about 90 kd."

Applicant's antigen composition as now claimed, comprises a tumor antigen, which is "identified" as comprising UTAA subunit, and after treatment with β-mercaptoethanol and separation by SDS-PAGE exhibits a molecular weight of 90-100 kd. The antigen of Real et al as a pI of 5.5. and about 90 kd. Although Applicant has urged that the pI is a distinguishing factor, the difference in isoelectric points reported is well within experimental error.

Applicant also urges that another "distinguishing factor" is that in comparison with the Real et al antigen, "out of 34 allogeneic melanoma cell lines, apparently only one was capable of absorbing FD serum, in contrast, UTAA has been found in about 70-75% of melanoma cell lines tested."

Applicant cannot rely on limitations not recited in the claims to now distinguish over the prior art.

Applicant has not presented any evidence to support the assertion that the prior art antigen does not anticipate that claimed.

Applicants amendments and/or new claims necessitate the following new grounds of rejection.

Claim 19 rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the

invention.

Claim 19 is indefinite because it now depends from a non-elected claim 47.

Claim 19 is rejected under 35 U.S.C. § 102(b) as being anticipated by Real et al US Patent 4 562 160.

Applicants have amended the claim to delete vaccine and include the limitations of "antigen composition".

Real et al US Patent disclose an antigen composition comprised of a tumor associated antigen within the molecular weight range of about 90-100 kd which may be used to generate monoclonal antibody. ((see the Abstract.)

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers relating to this application may be submitted to Group

180 by facsimile transmission. Papers should be faxed to Group 180 via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center number is (703) 308-4227. Papers may be submitted Monday-Friday between 8:00 am and 4:45 pm (EST). Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to H. F. Sidberry whose telephone number is (703) 308-0170.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Sidberry/hfs
November 25, 1994

CHRISTINE M. NUCKER
SUPERVISORY PATENT EXAMINER
GROUP 180